K100351

510(k) Summary

A. Submitter Information

MAR 16 2010

Submitter's name:	Codman & Shurtleff, Inc.
Address:	325 Paramount Drive Raynham, MA 02767
Telephone:	508-828-2840
Fax:	508-828-2777
Contact Person:	Joan Bartle
Date of Submission:	February 5, 2010

B. Trade/Device Name:	NEUROSCOUT™ Steerable Guidewire
Common Name:	Catheter Guidewire
Classification Name:	Wire, Guide, Catheter
Regulation Number:	870.1330

C. Predicate Device: AGILITY® Steerable Guidewire (K991646) (.012)
AGILITY® Steerable Guidewire (K001033) (.014)
AGILITY® Steerable Guidewire (K010511) (.016)

D. Device Description: The hydrophilically coated NEUROSCOUT 0.014 guidewires consist of a stainless steel wire core and a radiopaque platinum/tungsten coil on the distal tip. The basic principle of the guidewires is to act as a monorail that catheters can track over to reach a particular area of the neuro and peripheral vasculature. They have a nominal outside diameter of 0.014 inch and nominal overall length of up to 300 cm.

E. Intended Use: The NEUROSCOUT Steerable Guidewires are intended for selective placement of microcatheters and other devices within the neuro and peripheral vasculature.

F. Summary of technological characteristics of the proposed to the predicate device:

No new technological characteristics are being introduced with the proposed device. A comparison of the technological characteristics of the proposed device to the predicate device show the proposed device has the following same or similar technological characteristics to the device which received 510(k) clearance:

- Same intended use;
- Same operating principle;
- Same materials;

- Similar device dimensional specifications;
- Same shelf life and sterilization process;
- Similar manufacturing process.

G. Performance Data:

Preclinical testing data to demonstrate that the device performs according to its description and intended use were used to establish the performance characteristics of the modifications to this device. Clinical testing was not required to establish substantial equivalence. Testing was conducted in accordance with *FDA Guidance for Coronary and Cerebrovascular Guidewires, 1995* and included Tensile, Torque Strength, Torqueability, Tip Flexibility/Linear Stiffness, Kink Radius, Lubricity and Catheter Compatibility, Coating Integrity and Simulated Use. Biocompatibility screening was conducted to confirm that modifications did not affect the biocompatibility of the device. Animal studies were conducted to ensure that the user needs were adequately addressed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAR 1 6 2010

Codman & Shurtleff, Inc.
c/o Joan Q. Bartle
Project Manager, Regulatory Affairs
325 Paramount Drive
Raynham, MA 02767

Re: K100351
Trade/Device Name: NEUROSCOUT Steerable Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guidewire
Regulatory Class: Class II
Product Code: DQX
Dated: February 8, 2010
Received: February 12, 2010

Dear Ms. Bartle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100351

Device Name: NEUROSCOUT™ Steerable Guidewire

Indications for Use:

The NEUROSCOUT™ Steerable Guidewires are intended for selective placement of microcatheters and other devices within the neuro and peripheral vasculature.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachney

(Division Sign-Off)
Division of Cardiovascular Devices

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